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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,882	12/10/2001	Heidi Meyer	V-261.00	2886

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08/27/2003

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EXAMINER

CHEN BROWN, STACY

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 08/27/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,882

Applicant(s)

MEYER ET AL.

Examiner

Stacy B Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's election of Group I, claims 1-21, with traverse is acknowledged. Claims 1-21 are pending and examined. Claims 22-23 are cancelled.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3-5, 10, 15-16 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "said temperature" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 4 and 15 recite improper Markush group language. The claims should read "selected from the group consisting of ...and...".

Claims 10 and 20, "HAV is continuously produced for at least 60 days" is unclear. Does one culture produce for 60 days, or is a fresh culture replacing an older one and continuing production? Clarification is requested.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 8, 9, 11-13, 15, 16, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kistner *et al* (WO 96/15231). The claims are drawn to a method for continuous production of HAV comprising culturing VERO cells (serum-free culture) bound to microcarriers and infecting with HAV. The culture is incubated and HAV is propagated and continuously released into the cell culture medium. The virus is then harvested and purified. The cells are grown at a temperature of about 37 degrees Celsius bound to microcarriers. The cell culture is subcultured from a working cell bank and passaged by use of a microbial protease or a trypsin-like enzyme of a microbial origin, such as pronase.

Kistner teaches a method of cultivating, harvesting and purifying influenza virus that can be applied to HAV (abstract and page 14, lines 9-10, line 33, and page 15, line 5). The cell culture comprises VERO cells grown in protein-free media. The cells can be subcultured from a working cell bank (page 76, line 32) with a protease such as pronase (page 29, lines 24-28). The protein-free cell culture is infected with virus and incubated at 37 degrees Celsius (page 61, line 8). The cells are bound to a microcarrier having either a smooth surface or a porous surface (page 27, lines 11-12). Kistner's method produces HAV which remains in the cells and is released into the supernatant (page 31, lines 8-10). Applicant's claims encompass the HAV particles released in the supernatant of Kistner's method.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 6, 7, 14, 17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kistner *et al* (WO 96/15231) as applied to claims 1, 2, 4, 5, 8, 9, 11-13, 15, 16, 18 and 19 above, and further in view of Purcell *et al* (4,894,228), Leu *et al* (WO 95/24468), Pellegrini *et al* (5,607,851) and Shih *et al* (5,980,901).

Kistner fails to teach the production of HAV strain HM175/7. However, Purcell teaches the production and isolation of HM175/7 for vaccines (abstract and column 3, lines 53-57). It would have been obvious to use HM175/7 in Kistner's method of production. One would have been motivated to use HM175/7 because Kistner's method produces large quantities of vaccine antigens, and HM175/7 is used as a vaccine antigen because of its attenuating properties.

Kistner discloses that an attenuated virus can be produced according to their method and used for preparation of a vaccine (page 35, lines 25-26). One would have had a reasonable expectation of success that the HAV strain HM175/7 would have grown in Kistner's cell culture method because Purcell teaches that the preferred method of propagating HM175/7 is in cell culture.

Kistner is silent on the MOI when infecting cells with virus, however, Leu *et al* (WO 95/24468) teaches the production of HAV in MRC-5 cells (also suggests Vero cells can be used) bound to microcarriers, infected with a MOI of about 0.05 to 1 at a temperature of about 30-37 degrees Celsius (page 16, lines 20-21, page 17, lines 7-8). Pellegrini *et al* (5,607,851) uses a MOI of 0.5 to infect cells with HAV (col. 3, line 1). One would be motivated to infect the cells of Kistner with a MOI of 0.05 to 1, as it is a standard practice, as evidenced by Leu. One

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would have had a reasonable expectation of success that a MOI of 0.05 to 1 would have worked in Kistner's method because the methods are similar with regard to cell type and virus type.

Kistner is silent on the method of isolation of virus, however, Shih *et al* (5,980,901) teaches a method of isopycnic centrifugation of viral particles from media. One would have been motivated to use the method of isopycnic centrifugation because it is a standard method of purification, as evidenced by Shih. One would have had a reasonable expectation of success that isopycnic centrifugation would have separated the particles of Kistner from the media because Shih separates particles from media using the method.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

5. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number

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for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SBc
Stacy B. Chen
August 22, 2003

James C. Housel
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